

**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Original) A controller for a blood treatment equipment, said equipment comprising at least

a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation of a treatment liquid,

the controller being adapted to:

receive one or more entries of measured information measured during the course of a treatment procedure, calculate from said measured information a value of at least a significant parameter indicative of the progress of an extracorporeal blood treatment carried out by the equipment,

wherein the controller is also adapted to compare said calculated significant parameter to at least a prescribed reference value for the same parameter, and to generate at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment.

2. (Currently Amended) Controller according to claim 1, wherein the significant parameter is one chosen in the group comprising:

[[ - ]] the actual dialysance  $D_{Ti}$  or clearance  $K_{Ti}$  of a blood treatment unit associated with the equipment for a specific solute after a time  $T_i$  elapsed from the beginning of the treatment;

[[ -]] the concentration of a substance in the blood of a patient undergoing a treatment or the patient's plasmatic conductivity  $C_{pT_i}$  achieved at the elapsed time  $T_i$ ;

[[ -]] the dialysis dose  $K \cdot T_{T_i}$  achieved at the elapsed time  $T_i$ ;

[[ -]] the weight loss  $WL_{T_i}$  achieved at the elapsed time  $T_i$ ; and

[[ -]] a parameter proportional or known function of one or more of the above parameters.

3. (Currently Amended) Controller according to claim 1 ~~or~~ 2, wherein said measured information is ~~one~~ chosen ~~in~~ from the group comprising:

[[ -]] conductivity ~~of the~~ of the treatment liquid downstream of the treatment unit; and

[[ -]] concentration of a substance in the treatment liquid downstream of the treatment unit.

4. (Original) Controller according to claim 1, wherein the controller generates the output control signal responsive to said comparison for automatically controlling a fluid removal rate from said second compartment.

5. (Currently Amended) Controller according to claim 1 ~~to~~ 4, wherein the prescribed reference value comprises the total dialysis dosage value  $KT_p$  to be achieved at the end of the treatment, said controller determining, at time intervals during treatment:

[[ -]] an instantaneous clearance  $K_{T_i}$  or dialysance value  $D_{T_i}$  measured at treatment time  $T_i$ ,

[[ -]] an effective total dialysis dosage  $KT_{T_i}$  value which has been delivered at the elapsed treatment time  $T_i$ ,

[[ -]] at least one among an estimated remaining treatment procedure time  $T_{tr}$  and an estimated total treatment time  $T_{tot}$  required for achieving said 5 prescribed total dialysis dosage value  $KT_p$ .

6. (Original) Controller according to claim 5, wherein said controller is programmed for determining the estimated remaining treatment procedure time  $T_{tr}$  as a function of said total dialysis dosage value  $KT_p$ , the effective total dialysis dosage  $KT_{ti}$  achieved by time  $T_i$ , and of the instantaneous clearance  $K_{Ti}$  or dialysance value  $D_{Ti}$  measured at treatment time  $T_i$ .

7. (Original) Controller according to claim 5, wherein said controller is programmed for determining the estimated total treatment time  $T_{tot}$  as a function of said total dialysis dosage value  $KT_p$ , of the effective total dialysis dosage  $KT_i$  achieved by time  $T_i$ , and of the elapsed treatment time  $T_i$ .

8. (Original) Controller according to claim 6, wherein said controller, at each time interval, is programmed for updating the estimated total treatment time  $T_{tot}$  as sum of the elapsed treatment time  $T_i$  and of the estimated value of the remaining treatment procedure time  $T_{tr}$ .

9. (Currently Amended) Controller according to claim 6 or 7, wherein said prescribed parameter also comprises a prescribed total weight loss  $WL_p$  to be achieved at the end of the treatment, said controller being programmed for performing the following further steps at time intervals during treatment:

[[ -]] determining of an actual measured total weight loss  $WL_{Ti}$  achieved by time  $T_i$ ,  
and

[[ -]] setting of fluid removal rate UF from said second compartment for achieving a prescribed total weight loss  $WL_p$  substantially at the same time as the prescribed total dialysis dosage value  $KT_p$  is achieved.

10. (Original) Controller according to claim 9, wherein it is programmed for controlling, on an ongoing basis, the fluid removal rate as a function of the estimated remaining treatment procedure time  $T_{tr}$  or of estimated total treatment time  $T_{tot}$ .

11. (Original) Controller according to claim 10, wherein said controlling comprises setting of the fluid removal rate  $UF_{Ti}$  at time  $T_i$  equal to the prescribed total weight loss  $WL_p$  less the measured weight loss  $WL_{Ti}$  at time  $T_i$ , divided by the estimated remaining treatment time  $T_r$ , according to the formula:

$$UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tr}}$$

12. (Original) Controller according to claim 10, wherein said controlling step comprises setting of the fluid removal rate  $UF_{Ti}$  at time  $T_i$  equal to the prescribed total weight loss  $WL_p$  less the measured weight loss  $WL_{Ti}$  at time  $T_i$ , divided by a difference between the estimated total treatment time  $T_{tot}$  and the elapsed treatment time  $T_i$

according to the formula:  $UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tot} - T_i}$

13. (Currently Amended) Controller according to ~~any one of claims from claim 5 to 13~~, wherein it is programmed for recalculating and updating at regular time intervals during treatment the estimated total treatment time  $T_{tot}$  and/or the estimated remaining treatment time  $T_{tr}$ , on the basis of the most recent value or values of instantaneous clearance  $K_{Ti}$  or dialysance  $D_{Ti}$ .

14. (Currently Amended) Controller according to ~~any one of claims from claim 5 to 13~~, wherein it is programmed for recalculating and updating at regular time intervals during treatment the effective total dialysis dosage  $KT_{Ti}$  value, which has been delivered at the elapsed effective treatment time  $T_i$ .

15. (Currently Amended) Controller according to claim 5, wherein the instantaneous clearance value  $K_{Ti}$  or instantaneous dialysance value  $D_{Ti}$  is determined at treatment time  $T_i$ , by means of a method comprising the following sub-steps:

[[ - ]] sending at least a first liquid through the second compartment of the treatment unit,

[[ - ]] sending at least a second liquid through the second compartment of the treatment unit, the second liquid having conductivity or concentration for at least a solute different from that of the first liquid

[[ - ]] measuring the conductivity or concentration values of said substance in the treatment liquid downstream the treatment unit at least for both said first and for said second liquid, and

[[ - ]] calculating the instantaneous clearance  $K_{Ti}$  or instantaneous dialysance value  $D_{Ti}$  at least as a function of said measured conductivity or concentration values.

16. (Original) Controller according to claim 5, wherein the effective total dialysis dosage  $KT_{Ti}$  value, which has been delivered at the determined effective treatment time  $T_i$ , is calculated as an integration over time of effective instantaneous clearance  $K_{Ti}$  or instantaneous dialysance  $D_{Ti}$  values determined at the various regular time intervals  $T_i$ .

17. (Original) Controller according to claim 5, wherein the effective total dialysis dosage  $KT_i$  value, which has been delivered at the effective treatment time  $T_i$ , is calculated as the product of the treatment time  $T_i$  by a mean value of effective instantaneous clearance  $K_{Ti}$  or of instantaneous dialysance  $D_{Ti}$  values determined at the various regular time intervals  $T_i$ .

18. (Currently Amended) Controller according to ~~any one of claims from claim 1 to 4~~, wherein the prescribed parameter comprises the total clearance value  $KT_p$  to be achieved at the end of the treatment, and a prescribed total weight loss  $WL_p$  to be achieved at the end of the treatment, said controller being programmed for determining a prescribed rate  $R$  by dividing said total weight loss  $WL_p$  to be achieved at the end of the treatment by said total dialysis dose value  $KT_p$  to be achieved at the end of the treatment.

19. (Original) Controller according to claim 14, wherein it is programmed for controlling the rate of fluid removal from the second compartment of the blood treatment, said controlling comprising keeping said rate of fluid removal  $UF_{Ti}$  at time  $T_i$  substantially equal to the product of said prescribed rate  $R$  by the instantaneous clearance  $K_{Ti}$  or instantaneous dialysance value  $D_{Ti}$  measured at treatment time  $T_i$ .

20. (Currently Amended) Controller according to claim 5, wherein said controller, at each time interval, is programmed for:

[[ - ]] calculating a sum of the elapsed treatment time  $T_i$  with the calculated value of the remaining treatment procedure time  $T_{tr}[[ - ]]$ .

[[ - ]] comparing said sum with a minimum treatment time  $T_{min}$  and with a maximum treatment time  $T_{max}$ .

[[ -]] setting a total treatment time  $T_{tot}$  equal to the minimum treatment time  $T_{min}$ , if said sum is less than the minimum treatment time  $T_{min}$ ,

[[ -]] setting a total treatment time  $T_{tot}$  equal to the maximum treatment time  $T_{max}$ , if said sum is more than the minimum treatment time  $T_{max}$ ,

[[ -]] setting a total treatment time  $T_{tot}$  equal to said sum if the sum is neither less than the minimum treatment time  $T_{min}$  nor more than the minimum treatment time  $T_{max}$ .

21. (Currently Amended) Controller according to claim 20, wherein said prescribed parameter also comprises a prescribed total weight loss  $WL_p$  to be achieved at the end of the treatment, said controller being programmed for performing the following further steps at time intervals during treatment:

[[ -]] determining of an actual measured total weight loss  $WL_{Ti}$  achieved by time  $T_i$ , and

[[ -]] setting of fluid removal rate from said second compartment for achieving a prescribed total weight loss  $WL_p$  at said total treatment time  $T_{tot}$ .

22. (Original) Controller according to claim 21, wherein it is programmed for controlling, on an ongoing basis, the fluid removal rate  $UF_{Ti}$  at time  $T_i$  as a function of the total treatment time  $T_{tot}$  by setting the  $UF_{Ti}$  fluid removal rate at time  $T_i$  equal to the prescribed total weight loss  $WL_p$  less the measured weight loss  $WL_{Ti}$  at time  $T_i$ , divided by the difference between the calculated total treatment time  $T_{tot}$  and the elapsed treatment time  $T_i$ , according to the formula:

$$UF_{Ti} = \frac{WL_p - WL_{Ti}}{T_{tot} - T_i}$$

23. (Original) Controller according to claim 21, wherein it is programmed for recalculating and updating the total treatment time  $T_{tot}$  and/or the remaining treatment

time  $T_{tr}$  at regular time intervals during treatment, on the basis of the last or most recent instantaneous measured value or values of clearance  $K_{Ti}$  or dialysance  $D_{Ti}$ .

24. (Original) Controller according to claim 21, wherein it is programmed for recalculating and updating at regular time intervals during treatment the effective total dialysis dosage  $KT_{Ti}$  value which has been delivered at the elapsed effective treatment time  $T_i$ .

25. (Original) Controller according to claim 21, wherein the effective total dialysis dosage  $KT_i$  value, which has been delivered at the determined effective treatment time  $T_i$ , is calculated as an integration over time of effective instantaneous dialysis dosage values  $DT_i$  determined at the various regular time intervals  $T_i$ .

26. (Currently Amended) Controller according to claim 1 ~~or 5 or 18 or 20~~, wherein the prescribed reference value comprises a patient blood conductivity or concentration target  $C_{p_{end}}$ , said controller being programmed for controlling the conductivity or concentration of the treatment liquid entering the second compartment as a function of said blood conductivity or concentration target  $C_{p_{end}}$ .

27. (Original) Controller according to claim 5, wherein the prescribed reference value comprises a patient blood conductivity or concentration target  $C_{p_{end}}$  to be achieved, said controller being programmed for changing, if necessary, at each time interval, the conductivity or concentration of the treatment liquid entering the second compartment in order to have blood conductivity or concentration for a substance reaching said conductivity or concentration target  $C_{p_{end}}$  on or before said estimated total treatment time  $T_{tot}$ .



28. (Currently Amended) Controller according to claim 9, wherein the prescribed reference value comprises a patient blood conductivity or concentration target  $C_{p_{end}}$  to be achieved, said controller being programmed for changing, if necessary, at each time interval, the conductivity or concentration of the treatment liquid entering the second compartment in order to have blood conductivity or concentration for a substance reaching said conductivity or concentration target  $C_{p_{end}}$  on or before said estimated total treatment time  $T_{tot}$ .

29. (Currently Amended) Controller according to ~~anyone of claims from~~ claim 5 to 25, wherein the prescribed reference value comprises a patient blood conductivity or concentration target  $C_{p_{end}}$  to be achieved, said controller being programmed for performing the following steps at each time interval  $t_i$  during at least a part of said treatment:

[[ - ]] determining an interval target blood conductivity or concentration  $C_{p_i}$  for the patient's blood, relating to a elapsed time  $T_i$ , and

[[ - ]] modifying, if necessary, the conductivity or concentration for a substance  $C_d$  of treatment liquid entering the second compartment to have the patient plasmatic conductivity reaching the interval target  $C_{p_i}$ .

30. (Currently Amended) Controller according to claim 29, wherein the said modifying of treatment liquid conductivity or concentration  $C_d$  comprises the following sub-steps:

[[iii.]] ~~Determining~~ determining a calculated value  $C_{di}$  of the conductivity or concentration for a substance  $C_d$  as a function of the interval target  $C_{p_i}$  and of the measured instantaneous dialysance or clearance  $D_i$  or  $K_i$  for time  $T_i$ ,

[[iv.]] ~~Bringing~~ bringing the conductivity or concentration for a substance  $C_d$  of treatment liquid entering the second compartment to said calculated value  $C_{di}$ .

31. (Original) Controller according to claim 30, wherein the said determining step uses the following formula:

$$C_d = C_{di} = \frac{C_{Pi} - C_{Pi-1} e^{-\frac{D_i}{V_0}(T_i - T_{i-1})}}{1 - e^{-\frac{D_i}{V_0}(T_i - T_{i-1})}}$$

wherein  $V_0$  represents the urea distribution volume for the patient.

32. (Original) Controller according to claim 30, wherein the said determining step uses the following formula:

$$C_d = C_{di} = \frac{C_{Pi} - C_{Pi-1} e^{-\frac{K_i}{V_0}(T_i - T_{i-1})}}{1 - e^{-\frac{K_i}{V_0}(T_i - T_{i-1})}}$$

wherein  $V_0$  represents the urea distribution volume for the patient.

33. (Currently Amended) Controller according to claim 29, wherein it is programmed for calculating said interval target blood conductivity or concentration  $C_{pi}$  for the patient's blood relating to a time interval  $T_i$ , according to the following steps:

[[ - ]] evaluating if the elapsed treatment time  $T_i$  is more or less of a prescribed value  $T_p$ ,

[[ - ]] assigning as interval target blood  $C_{pi} = C_{p_{end}} + A$ , wherein  $A$  is a positive value, if  $T_i$  less than  $T_p$ , and

[[ - ]] assigning as interval target blood  $C_{pi} = C_{p_{end}}$ , if  $T_i$  more than or equal to  $T_p$ .

34. (Currently Amended) Controller according to claim 33, wherein the prescribed value  $T_p$   ~~$T_p$~~   $T_p$  is less than  ~~$T_{tot}$~~   $T_{tot}$ .

35. (Original) Controller according to claim 34, wherein the prescribed value  $T_p$  is equal to  $T_{tot}$  reduced by one hour.

36. (Currently Amended) Blood treatment equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation of a treatment liquid, and a controller according to ~~anyone of the preceding~~ claims claim 1.

37. (Original) Equipment according to claim 36, comprising measuring means connected to the controller for measuring at least one of:

conductivity of the of the treatment liquid downstream the treatment unit; or  
concentration of a substance in the treatment liquid downstream the treatment unit.

38. (Original) Equipment according to claim 36, comprising measuring means for measuring at least one of:

conductivity of the of the treatment liquid upstream the treatment unit; or  
concentration of a substance in the treatment liquid upstream the treatment unit.

39. (Original) Equipment according to claim 37, comprising measuring means for measuring comprises a conductivity cell or an ion selective sensor or a urea sensor, operating on a conduit downstream the treatment unit.

40. (Original) Equipment according to claim 38, comprising measuring means for measuring comprises a conductivity cell or an ion selective sensor, operating on a conduit upstream the treatment unit.

41. (Currently Amended) Equipment according to claim 36 also including entry means for entering prescribed reference value or values for the significant parameter or parameters.

42. (Original) Equipment according to claim 36, comprising a variable speed ultrafiltration pump, in which the controller is programmed to generate a control signal to automatically control the fluid removal rate from said second compartment by controlling the variable speed ultrafiltration pump.

43. (Original) Equipment according to claim 36, wherein the controller is associated with an alert device, and the controller is programmed to activate said alert device if the expected treatment procedure time or remaining hemodialysis treatment time are not within a prefixed range.

44. (Currently Amended) Equipment according to claim ~~48~~ 36, in which the controller is associated with a display screen adapted to display at the time intervals  $T_i$  one or more of the values of the group comprising:

[[ - ]] remaining time  $T_{tr}$ ,

[[ - ]] total treatment time  $T_{tot}$ ,

[[ - ]] clearance of dialysance measurements at the elapsed time  $T_i$ ,

[[ - ]] achieved dialysis dosage  $KT_{Ti}$  after  $T_i$  time,

[[ - ]] achieved weight loss  $WL_{Ti}$  after  $T_i$  time,

[[ - ]] achieved patient's conductivity after  $T_i$  time,

[[ - ]] prescribed value for more of the significant parameters, and

[[ - ]] a value proportional to one or more of the above values.

45. (Currently Amended) A control method for a blood treatment equipment, said equipment comprising at least a treatment unit including a semipermeable membrane separating the treatment unit in a first compartment for the circulation of blood and in a second compartment for the circulation of a treatment liquid, the method comprising the steps of:

[[ - ]] receiving one or more entries of measured information measured during the course of a treatment procedure,

[[ - ]] calculating from said measured information a value of at least a significant parameter indicative of the progress of an extracorporeal blood treatment carried out by the equipment, and

[[ - ]] comparing said calculated significant parameter to at least a prescribed reference value for the same parameter, and generating at least one output control signal responsive to said comparison for automatically controlling one or more operations performed by the equipment.

46. (Currently Amended) Method according to claim 45, wherein the significant parameter is one chosen ~~in~~ from the group comprising:

[[ - ]] the actual dialysance  $D_{Ti}$  or clearance  $K_{Ti}$  of a blood treatment unit associated with the equipment for a specific solute after a time  $T_i$  elapsed from the beginning of the treatment;

[[ - ]] the concentration of a substance in the blood of a patient undergoing a treatment or the patient's plasmatic conductivity  $Cp_{Ti}$  achieved at the elapsed time  $T_i$ ;

[[ - ]] the dialysis dose  $K \cdot T_{Ti}$  achieved at the elapsed time  $T_i$ ; and

[[ - ]] the weight loss  $WL_{Ti}$  achieved at the elapsed time  $T_i$ ;

[[ -]] a parameter proportional or known function of one or more of the above parameters.

47. (Currently Amended) Method according to claim 45 ~~or 46~~, wherein said measured information is one chosen ~~in~~ from the group comprising:

[[ -]] conductivity of the of the treatment liquid downstream the treatment unit; and

[[ -]] concentration of a substance in the treatment liquid downstream the treatment unit.

48. (Currently Amended) Method according to claim 4 45, wherein the controller generates the output control signal responsive to said comparison for automatically controlling a fluid removal rate from said second compartment.

49. (Currently Amended) Method according to ~~anyone of claims from~~ claim 45 ~~to 48~~, wherein the prescribed reference value comprises the total dialysis dosage value  $KT_p$  to be achieved at the end of the treatment, said method comprising the step of determining, at time intervals during treatment:

[[ -]] an instantaneous clearance  $K_{Ti}$  or dialysance value  $D_{Ti}$  measured at treatment time  $T_i$ ,

[[ -]] an effective total dialysis dosage  $KT_{Ti}$  value which has been delivered at the elapsed treatment time  $T_i$ , and

[[ -]] at least one among an estimated remaining treatment procedure time  $T_r$  and an estimated total treatment time  $T_{tot}$  required for achieving said prescribed total dialysis dosage value  $KT_p$ .

50. (Original) Method according to claim 49, wherein it comprises recalculating and updating at regular time intervals during treatment the estimated total

treatment time  $T_{\text{tot}}$  and/or the estimated remaining treatment time  $T_{\text{tr}}$ , on the basis of the most recent value or values of instantaneous clearance  $K_{\text{Ti}}$  or dialysance  $D_{\text{Ti}}$ .

51. (Currently Amended) Method according to ~~any one of claims from~~ claim 49, wherein it comprises recalculating and updating at regular time intervals during treatment the effective total dialysis dosage  $KT_{\text{Ti}}$  value, which has been delivered at the elapsed effective treatment time  $T_i$ .

52. (Original) Method according to claim 49, wherein the effective total dialysis dosage  $KT_{\text{Ti}}$  value, which has been delivered at the determined effective treatment time  $T_i$ , is calculated as an integration over time of effective instantaneous clearance  $K_{\text{Ti}}$  or instantaneous dialysance  $D_{\text{Ti}}$  values determined at the various regular time intervals  $T_i$ .

53. (Original) Method according to claim 49, wherein the effective total dialysis dosage  $KT_{\text{Ti}}$  value, which has been delivered at the effective treatment time  $T_i$ , is calculated as the product of the treatment time  $T_i$  by a mean value of effective instantaneous clearance  $KT_{\text{Ti}}$  or of instantaneous dialysance  $D_{\text{Ti}}$  values determined at the various regular time intervals  $T_i$ .

54. (Original) Method according to claim 45, wherein the prescribed parameter comprises the total clearance value  $KT_{\text{P}}$  to be achieved at the end of the treatment, and a prescribed total weight loss  $WL_{\text{P}}$  to be achieved at the end of the treatment, said method including the steps of determining a prescribed rate  $R$  by dividing said total weight loss  $WL_{\text{P}}$  to be achieved at the end of the treatment by said total dialysis dose value  $KT_{\text{P}}$  to be achieved at the end of the treatment.

55. (Currently Amended) Method according to claim 45 ~~or 54~~, wherein the prescribed reference value comprises a patient blood conductivity or concentration

target  $C_{p_{end}}$ , said method including the steps of controlling the conductivity or concentration of the treatment liquid entering the second compartment as a function of said blood conductivity or concentration target  $C_{p_{end}}$ .

56. (Original) Method according to claim 45, wherein the prescribed reference value comprises a patient blood conductivity or concentration target  $C_{p_{end}}$  to be achieved, said method including the steps of changing, if necessary, at each time interval, the conductivity or concentration of the treatment liquid entering the second compartment in order to have blood conductivity or concentration for a substance reaching said conductivity or concentration target  $C_{p_{end}}$  on or before said estimated total treatment time  $T_{tot}$ .

57. (Currently Amended) Method according to claim 54, wherein the prescribed reference value comprises a patient blood conductivity or concentration target  $C_{p_{end}}$  to be achieved, said controller being programmed for changing, if necessary, at each time interval, the conductivity or concentration of the treatment liquid entering the second compartment in order to have blood conductivity or concentration for a substance reaching said conductivity or concentration target  $C_{p_{end}}$  on or before said estimated total treatment time  $T_{tot}$ .

58. (Currently Amended) Program storage means including a program for a programmable controller, the program when run by the controller programming the controller to carry out the steps according to ~~the preceding method claims~~ claim 45.

59. (Original) Program storage means according to claim 58 comprising an optical data carrier and/or a magnetic data carrier and or a volatile memory support.